K013250

OCT 26 2001

Attachment IV

Special Premarket Notification Summary of Safety and Effectiveness

Applicant:

W.L. Gore & Associates, Inc.
3450 West. Kiltie Lane
P.O. Box 500
Flagstaff, AZ 86002-0500

Contact

Timothy J. Rynn

Date Prepared

24 October 2001

Trade or Proprietary Name

GORE-TEX® Vascular Graft; GORE-TEX® Stretch Vascular Graft

Common or Usual Name

Vascular Graft Prosthesis

Classification Name

Vascular Graft Prosthesis

Device Predicates

GORE-TEX® Vascular Grafts and GORE-TEX® Stretch Vascular Grafts

Device Description

GORE-TEX® Vascular Grafts and GORE-TEX® Stretch Vascular Grafts are composed of expanded polytetrafluoroethylene (ePTFE), and utilize an ePTFE basetube radially reinforced with a thin layer of ePTFE film wrapped around the basetube circumference. The device modification that is the subject of this Special 510(k) involves an alternative thin ePTFE film wrapped around the basetube circumference for use on vascular grafts configured for pediatric shunt.

Statement of Intended Use

GORE TEX Vascular Grafts and GORE-TEX Stretch Vascular Grafts are intended for use for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requireing vascular replacement, or for other vascular procedures.

Substantial Equivalence

The applicant device is substantially equivalent in design, materials, and intended use to currently marketed ePTFE vascular grafts prostheses. No new types of safety and effectiveness issues are raised by the proposed modification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 6 2001

Mr. Tomothy J. Rynn
Regulatory Affairs
W.L. Gore & Associates, Inc.
3450 West Kiltie Lane
P.O. Box 500
Flagstaff, AZ 86002-500

Re: K013250
Trade Name: Gore-Tex® Vascular Graft; Gore-Tex® Stretch Vascular Graft
Regulation Number: 21 CFR 870.3460
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II (two)
Product Code: DSY
Dated: September 27, 2001
Received: September 28, 2001

Dear Mr. Rynn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment II

Indications For Use Statement

510(k) Number (if known) K013250

Device Name: GORE-TEX® Vascular Graft; GORE-TEX® Stretch Vascular Graft

INDICATIONS FOR USE:

GORE TEX Vascular Grafts and GORE-TEX Stretch Vascular Grafts are intended for use for replacement or bypass of diseased vessels in patients suffering occlusive or aneurysmal diseases, in trauma patients requiring vascular replacement, or for other vascular procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K013250

Prescription Use X OR Over-The-Counter Use ___
(per 21 CFR 801.109)

(Optional Format 1-2-96)